REMARKS

The Office Action mailed August 11, 2004, has been carefully reviewed and Applicants note with appreciation the identification of allowable subject matter.

By this Amendment, Applicants have canceled claims 1-3, 5, 6, 11, 12 and 31, amended claims 4, 7-10, 19, 32 and 33, and added claims 34-36. Claims 4, 7-10, 13-19 and 32-36 are pending in the application. Claims 4 and 34 are independent.

The Examiner objected to claims 3 and 8-10 as containing informalities which Applicants have corrected herein.

The Examiner rejected claims 1, 2 and 31 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,618,587 to Premoli et al., by U.S. Patent No. 4,724,216 to Young et al., and by U.S. Patent No. 3,934,977 to Cleaver. The Examiner also rejected claims 1 and 3 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,953,172 to Shapiro et al.

By this Amendment, Applicants have cancelled claims 1-3 and 31, thereby removing the basis for these rejections.

The Examiner rejected claims 4-9, 12-16, 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over European Patent Application Number 0330892 to Gambro AB ("Gambro") in view of U.S. Patent No. 5,780,438 to Gilchrist et al. ("Gilchrist"). The

Examiner also rejected claim 17 under 35 U.S.C. 103(a) as being unpatentable over Gambro in view of Gilchrist and further in view of the article "Patient Monitoring" by Togawa, and rejected claims 32 and 33 as being unpatentable over Gambro in view of Gilchrist and further in view of U.S. Patent No. 3,912,455 to Lichtenstein. The Examiner objected to claims 10 and 11 as being dependent on a rejected base claim but stated that claims 10 and 11 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

As set forth in claim 4 as amended herein, the present invention is directed to a method for determining ion concentration of the blood of a patient in citrate anti-coagulated haemo-dialysis and/or haemo-filtration by measuring the ion concentration in the dialysate. According to the method, before the concentration of a target ion in the dialysate is measured, the addition of citrate to the blood circulation as is undertaken during a citrate dialysis procedure is temporarily interrupted in order to prevent complexing of the target ion with the citrate. Thereafter, the concentration of the target ion in the dialysate is measured and, based on this measurement, the ion concentration of the blood is determined. This is not shown or suggested by Gambro whether taken alone or in view of Gilchrist.

Gambro is directed to a dialysis system in which a parameter measured after the dialyser is compared with a set value before the dialyser in order to calculate a blood parameter that is altered by the measured parameter. Through adjustment of the parameter set value, the associated blood parameter may be controlled. However, the recognition of a relationship between a dialysis liquid parameter and the blood in a traditional dialysis application such as Gambro does not teach or suggest the specific invention being claimed by the present invention.

Particularly, there is nothing in Gambro that teaches a citrate anti-coagulated dialysis method which, as explained in the specification of the present invention at pages 1-4, is distinct from traditional dialysis approaches that rely on heparin to prevent blood coagulation and which do not involve or suggest the citrate complexing considerations of the present invention. Specifically, there is nothing in Gambro to teach a temporary interruption in the adding of citrate to the blood, preparatory to determining the ion concentration in the dialysate, during citrate anti-coagulated haemo-dialysis and/or haemo-filtration. As claimed, the temporary interruption serves to prevent the complexing of the ion so that an accurate measure of the ion concentration in the

dialysate may be taken, from which the ion concentration in the blood may be determined. This is not shown by Gambro.

Nor does Gilchrist provide the necessary teaching of such a citrate anti-coagulated haemo-dialysis and/or haemo-filtration method. Gilchrist is directed to a dialysis fluid having a sodium bicarbonate ion buffering agent that does not result in the precipitation of insoluble carbonates in the peritoneum during continuous ambulatory peritoneal dialysis (CAPD). The dialysis fluid also has an osmotic agent that includes a mixture of peptides obtained by the action of a proteolytic enzyme on a protein source of casein or whey proteins. This osmotic agent contributes about 25-100 mOsm/Kg to the total desired osmolality of between 100 and 400 mOsm/Kg, with the balance being provided by physiological salts (see column 5, lines 5-18). These salts are listed in column 5, lines 31-36, and can include citrate, as cited by the Examiner. However, this passing reference to the optional inclusion of citrate within a specific dialysis fluid in order to reach a desired total osmolality in no way teaches or suggests the use of citrate in a citrate anti-coagulated haemo-dialysis and/or haemo-filtration process for ion concentration measurement in a dialysate as claimed by the present invention.

Nor would the use of the dialysis fluid of Gilchrist within the dialysis system of Gambro result in the present invention as claimed herein. Accordingly, favorable reconsideration and allowance of claim 4 as amended herein is requested. Claims 7-10 and 13-19 are also in condition for allowance as claims properly dependent on an allowable base claim, for the subject matter contained therein, and in accordance with the Examiner's identification of allowable subject matter.

As set forth in new claim 34, the method of the present invention by which ion concentration in the dialysate is used to determine the ion concentration in the blood within a citrate anti-coagulated dialysis process, may also be realized by releasing the target ion from citrate complexing (as was previously set forth in claim 6). Separation of the ion from the citrate complex is achieved by lowering the pH of the dialysate, after which the ion concentration in the dialysate is determined and used to determine the ion concentration in the blood. This method is also well beyond the fair teaching of Gambro and Gilchrist as set forth above. Favorable consideration and allowance of claim 34 are therefore requested.

Claims 35 and 36 are in condition for allowance as claims properly dependent on an allowable base claim, for the subject

matter contained therein, and in accordance with the Examiner's identification of allowable subject matter.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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